UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

IN RE: PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	)	MDL NO. 1456
	)	CIVIL ACTION: 01-CV-12257-PBS
	)	Judge Patti B. Saris
THIS DOCUMENT RELATES TO *U.S. ex rel. Ven-A-Care of the Florida Keys, Inc. v. Abbott Laboratories, Inc.*, No. 06-CV-11337-PBS	)	Magistrate Judge Marianne B. Bowler

ABBOTT'S MEMORANDUM IN SUPPORT OF ITS MOTION TO COMPEL TESTIMONY OF GOVERNMENT WITNESSES

INTRODUCTION

Through this motion, defendant Abbott Laboratories, Inc. ("Abbott") respectfully asks the Court to compel deposition testimony from nine current or former federal government employees that Government counsel has obstructed through assertion of the deliberative process privilege. There can be no legitimate dispute that the specific areas of inquiry put at issue by this motion are directly relevant to this case. Similar to its approach for documents withheld under the deliberative process privilege, Government counsel has disregarded entirely the potential relevance of this testimony to Abbott's defenses. Government counsel has instead simply instructed its witnesses not to provide testimony regarding many of its internal deliberations of central relevance to this case. No judgment, sense of fairness, or any notion of a balancing test has been applied in this wooden approach. Nor has the Government made any legitimate effort to consider or articulate what specific harm would arise if the testimony were allowed to go forward under a protective order in this case.

The specific questioning put at issue in this motion, along with counsel's instructions not to answer and related colloquy, are set forth in Exhibit 1. Abbott expects the Court's review of the selected testimony will demonstrate that Government counsel's muzzle has little to do with

the policies underlying the deliberative process privilege, and everything to do with concealing evidence unfavorable to the Government's claims.

The issues upon which Abbott has inquired, and which are the subject of this motion, are basic. They can be grouped into the following areas:

- Why did CMS choose to permit the Medicare and Medicaid programs to continue paying based on AWP when officials knew that there was a "spread" between AWP and acquisition costs?

- To what extent did Medicare and Medicaid continue to pay based on AWP because of considerations such as cross-subsidization, patient access to care, and political expedience? In particular, to what extent did the inadequacy of Medicare and Medicaid payments for cost-intensive infusion-related services impact CMS's decision-making?

- To what extent did Medicare and Medicaid decide not to increase dispensing, administration, or other service fees because of the "spread" that existed between AWP and acquisition cost?

- What deliberations did CMS have regarding what would be a reasonable margin to be paid to Medicare and Medicaid providers to dispense or administer drugs to beneficiaries?

- Why did CMS continue to approve state Medicaid plans that called for reimbursement at relatively small percentage discounts off of AWP (*e.g.*, AWP less 10%) when OIG, GAO, and other sources told CMS that the discounts, particularly for generic drugs, were much greater than that?

- What alternatives did CMS consider to AWP, such as use of Average Manufacturer Price ("AMP") data, and why did CMS not pursue those alternatives?

- What did CMS discuss with OIG at entrance and exit conferences when OIG told CMS that Medicare and Medicaid were paying in excess of acquisition costs, often by more than ten times, for drugs?

- Was it the understanding of the CMS officials who actually ran the Medicare and Medicaid programs that state and federal laws required Medicare and Medicaid to base payments upon AWP, regardless of whether, and the extent to which, those AWPs were inflated?

- Why did CMS not set Federal Upper Limits for the Subject Drugs?

Given this Court's familiarity with the core issues in this case, the relevance of these areas of inquiry—and the unfairness of the Government's refusal to allow answers given its position in this case—will be self-evident and should require little if any explanation from Abbott. No litigant should be permitted to thwart discovery as the Government has done here.

What follows are examples from the depositions of three key witnesses—Robert Vito, Larry Reed, and Robert Niemann—that illustrate why the Court should grant Abbott's motion to compel and put an end to the Government's tactics.

Example 1: Robert Vito

Robert Vito, a Regional Inspector General of OIG, has been heavily involved in investigating Medicare and Medicaid's payment for drugs since at least the early 1990s. Mr. Vito's office (OIG's Office of Evaluations and Inspections, Region 3) has authored numerous reports concerning AWP, and he has personally participated in numerous "entrance and exit conferences" where OIG's findings were discussed with key CMS officials. *See* Vito Dep. at 164-66 (Ex. 2). Mr. Vito has also attended numerous conferences attended by state Medicaid pharmacy personnel and/or industry representatives where Government drug payment policies were discussed. *See id.* at 39-45. In short, Mr. Vito had broad and in-depth exposure to the AWP issue, and can provide valuable insight regarding issues of fundamental importance to this case.

Government counsel obstructed Mr. Vito's deposition in areas of particular importance to Abbott's defenses. One example of this obstruction relates to discussions that Mr. Vito recalled with HCFA officials on how the margin made by providers on drugs was being used to cross-subsidize inadequate payment for labor-intensive home infusion and respiratory therapy. These discussions echo multiple public statements made by industry representatives and even unnamed

CMS officials in the press.[1] Unfortunately, before we could learn more about those discussions from Mr. Vito, Government counsel shut down the questioning:

> Q. Do you recall conversations that you were involved in where HCFA acknowledged that respiratory [and] infusion drug providers relied upon reimbursement rates for drugs to cover services?
>
> MR. DRAYCOTT: Objection, you can answer to the extent it doesn't reveal the contents of communications and deliberations occurring at entrance or exit conferences with CMS.
>
> THE WITNESS: Yes.
>
> * * *
>
> Q. And do you recall having the conversations at the exit and entrance conversation, at those meetings?
>
> A. Yes.
>
> Q. Can you tell me about those discussions?
>
> MR. DRAYCOTT: Objection. I instruct you not to answer to the extent it would reveal the communications and deliberations that occurred at those exit and entrance conferences.
>
> BY MR. TORBORG: Because of that, are you accepting the instruction not to answer?
>
> A. Yes, sir.

Id. at 652:12-21, 654:2-15.

[1] *See, e.g.*, 2002 Statement from National Alliance for Infusion Therapy/National Home Infusion Association to Congress ("For home infusion therapy, the drug payment is the only available payment mechanism for the services that are essential to providing good quality care.") (Ex. 3); Myers & Stauffer Dispensing Fee Study for the Texas Vendor Drug Program, at 24 (finding average dispensing fee for pharmacies dispensing intravenous/home infusion prescriptions of $41.75, and noting: "Although typical dispensing fees reimburse less than the dispensing costs of intravenous pharmacies, they are generally able to break even based on the margin allowed on ingredient cost reimbursement") (Ex. 4); Statement of Thomas Connaughton, American Association of Homecare, *Medicare Drug Reimbursements: A Broken System For Patients And Taxpayers*, Before the Committee on Energy and Commerce, U.S. House of Representatives (Sept. 21, 2001) ("There is little question that these criticisms [of AWP] are correct – if the payment 'buys' drugs only. In actual fact, the drug payment calculated on the basis of AWP has been used for far more than that. With regard to inhalation and infusion therapy in the home setting, the drug payment is the only available payment mechanism for needed functions that are essential to providing good quality care. In other words, the spread between the provider and suppliers' acquisition cost and Medicare reimbursement under Medicare Part B must cover all functions and services.") (Ex. 5); *Clinton Plans to Revive Acquisition Cost Issue*, Eli's Home Care Week, 2001 (noting: "In response to the OIG report, HCFA acknowledged that respiratory and infusion drug providers rely on the reimbursement rate to cover services for which Medicare does not currently reimburse.") (Ex. 6).

> Q. . . . Do you recall Mr. Vito having a discussion about the need to draw a distinction between infusion and inhalation drugs and outpatient drugs such as pills and patches in connection with the average wholesale price debate?
>
> A. Yes.
>
> * * *
>
> Q. Do you recall having those conversations with HCFA?
>
> A. Yes.
>
> Q. Do you have any of those conversations outside of the exit and entrance conversations—conferences?
>
> A. I don't think so.
>
> Q. Will you tell me about the conversations that you had regarding that distinction with HCFA
>
> MR. DRAYCOTT: Objection. I instruct you not to answer to the extent that those communications occurred in an entrance or exit conference.
>
> THE WITNESS: Right, no.

Id. at 687:11-17, 689:4-17.

Example 2: Larry Reed

Since 1990, Larry Reed has held key positions at CMS charged with regulating what State Medicaid programs pay for drugs. *See* Reed Tr. at 55-56, 61-63 (Ex. 7). He is currently the co-leader of the CMS "Pharmacy Team." *Id.* at 77. As with Mr. Vito, Government counsel asserted the deliberative process privilege liberally at Mr. Reed's deposition to thwart key areas of Abbott's questioning. For example, Mr. Reed was not permitted to testify about conversations held within CMS regarding what to do about OIG's findings of large percentage spreads for generic drugs when CMS decided whether to approve state payment rates for drugs:

> Q. Did you have discussions about the significantly greater difference between AWP and acquisition costs for generic drugs as opposed to branded drugs?
>
> MS. MARTINEZ: Objection, form.

MS. POLLACK: Objection, form.

THE WITNESS: I believe we had those discussions.

BY MR. TORBORG:

Q. Who were those discussions with?

MS. MARTINEZ: Objection, privilege.

MR. TORBORG: We have to decide who the discussions were with before we can decide what privilege applies.

MS. MARTINEZ: No, the discussions were within HCFA, and if they related to an anticipated decision by HCFA, then it would be privileged and then you would be instructed not to answer. If you had a discussion with somebody in the outside that's not related to a policy decision like that, you can—you can answer.

THE WITNESS: I can't answer.

BY MR. TORBORG:

Q. So you had discussions within HCFA about the significantly greater difference between acquisition costs and AWP for generic drugs as compared to branded drugs, correct?

MS. MARTINEZ: Objection, form.

THE WITNESS: We did have those discussions.

BY MR. TORBORG:

Q. And I'm not permitted to probe your memory here today because you've been instructed not to answer, correct?

A. Correct.

* * *

Q. I'm trying to . . . figure out what decision or policy those discussions related to.

A. The decision would be how to look at this and reviewing a state plan.

Q. And whether or not to approve or disapprove the plan?

A. That could be part of that decision.

Q. Which would ultimately determine how much providers were paid for drugs, correct?

A. Correct.

Id. at 519:9-521:15, 523:3-13. Nor was Mr. Reed permitted to testify about deliberations held within HCFA regarding the sufficiency of Medicaid payments for professional services associated with providing drug-related therapies to beneficiaries:

> Q. And do you recall discussions in your current HCFA about the cost of pharmacies to provide professional services other than dispensing prescriptions, such as therapeutic intervention, patient education and physician consultation? . . .
>
> A. Yes.
>
> Q. Can you tell me about those discussions?
>
> MS. MARTINEZ: Objection, privileged. To the extent that those discussions were done in anticipation of a decision or a proposed rulemaking or another decision at HCFA, you're instructed not to answer. Otherwise, you can answer.
>
> THE WITNESS: I can't answer.
>
> BY MR. TORBORG:
>
> Q. Because of the privilege issue?
>
> A. Correct.
>
> Q. Okay. What policy does that – do those deliberations relate to?
>
> A. There are policies—and I don't remember the format that they're in—on other services. It goes—they go by different names, but other services that pharmacists provide that would be reimbursed separate from ingredient cost and dispensing fee.
>
> Q. Okay. So HCFA had discussions about a policy on that issue; is that fair to say?
>
> A. Yes.
>
> Q. Because of the instruction of counsel, I'm not going to be allowed to learn about those through questioning of you; is that right?
>
> A. Correct.

Id. at 492:17-494:7.

Example 3: Robert Niemann

Mr. Reed's counterpart on the Medicare side of CMS was Robert Niemann. *See* Vito Dep. at 164-66 (indicating Reed and Niemann appeared to be the most knowledgeable about Medicaid and Medicare drug payment policies, respectively). Government counsel shut down important areas of Mr. Niemann's testimony, too. For example, Abbott was not permitted to learn about CMS's deliberations on whether its concerns over beneficiary access to care, or politics, may have perpetuated the use of AWP:

> BY MR. COOK: Q. In any of these conversations relating to the possibility of abandoning AWP and going to estimated acquisition cost, did any of the individuals that you've described ever raise concerns about what the consequences would be to beneficiaries' access to care or other program goals of going to EAC?
>
> MS. OBEREMBT: Objection on the grounds of the deliberative process privilege. I'll instruct you not to answer.
>
> BY MR. COOK: Q. Did politics ever play a role in the Medicare program's decision to continue to use average wholesale price rather than use estimated acquisition costs to establish its maximum allowable payment amount for drugs?
>
> MS. OBEREMBT: Objection to the extent you're asking him about discussions with agency personnel, where a policy decision was made. I have to instruct you not to answer that, too, I think.

Niemann Dep. at 199:14-200:2, 200:11-19 (Ex. 8).

These are just examples of a larger problem that has tainted this litigation. Abbott respectfully requests that the Court overrule the Government's objections to each of the requests listed in the chart attached as Exhibit 1 and compel the Government to respond fully.[2] Obtaining answers to these questions is clearly relevant to Abbott's ability to build its defense in this case.

[2] Excerpts from the relevant deposition transcripts are attached as Exhibits 2, 7, 8, and 16.

ARGUMENT

I. THE SUBJECT MATTERS CONTAINED IN THE QUESTIONING AT ISSUE IN THIS MOTION ARE HIGHLY RELEVANT.

Abbott's prior briefing has explained in detail why the deliberative process privilege should be strictly applied here, if at all, given that the Government put its knowledge and deliberations at issue by bringing a lawsuit alleging that it was misled into paying excessive payments for drugs. *See Dep't of Econ. Dev. v Arthur Andersen & Co.*, 139 F.R.D. 295, 299 (S.D.N.Y. 1991)) ("Where the adjudication of fraud claims turns upon issues of knowledge, reliance, and causation, direct evidence of the deliberative process is irreplaceable."); *Williams v. City of Boston*, 213 F.R.D. 99, 102 (D. Mass. 2003) (when "the 'decision-making process [of a government entity] itself is the subject of the litigation,' it is inappropriate to allow the deliberative process privilege to preclude discovery of relevant information.") (*quoting Burka v. NYC Transit Auth.*, 110 F.R.D. 660, 667 (S.D.N.Y. 1986)).

There can be little dispute that high-level state and federal officials were well aware that the AWPs reported in the national compendia were not, particularly for generic drugs, a reliable indicator of the prices at which pharmacists and physicians purchased drugs. Despite rampant knowledge that AWP overstated the true costs of drugs to providers, Congress, CMS, and nearly all the 50 states continued to base Medicare and Medicaid payments to physicians and pharmacies for providing the drugs at issue in this case upon AWPs found in the compendia. Indeed, even today, nearly all of the state Medicaid programs base payment for ingredient costs on compendia AWPs. Abbott's discovery—including the questioning at issue in this motion—has focused on the obvious question: Why? Was CMS misled, as it now claims, or did it make a deliberate policy choice to pay some amount above acquisition costs, as Abbott contends?

Government counsel pretends there could be only one answer to this question, and that any discovery about Government reimbursement policy is "irrelevant." Emphasizing the alleged "mega-spreads" for the generic drugs at issue here, Government counsel suggests that Congress, CMS, and the states could never have knowingly permitted such "inflated" payments and, thus, there is simply no need to bother looking behind the curtain into the Government's decision-making on drug payments. *See, e.g.*, Dkt. No. 4869 at 2-3, 15-17 (claiming Abbott "created" mega-spreads ranging from 275% to 1784%, that mega-spreads are in-and-of themselves egregious misconduct, and that Judge Saris' prior rulings in an unrelated case rendered discovery into why the Government choose to maintain an AWP-based payment system "irrelevant").[3]

But there is evidence, including the obstructed deposition testimony put at issue here, that demonstrates that the AWP story is more complicated than that. The obstructed testimony goes to the heart of this case and must be allowed to come into the factual record. Take, for example, the aborted testimony of Mr. Vito, quoted *supra* at 4-5. This testimony suggests that CMS may have deliberately allowed payment of a margin on acquisition cost for infusion and inhalation products to compensate for insufficient dispensing or professional service fees. This is particularly likely since, at the same time that Medicare moved from AWP-based reimbursement to ASP-reimbursement for these types of drugs, CMS dramatically increased the dispensing and service payments to these inhalation and home infusion providers.[4] If the AWP spread were

[3] Plaintiffs' "mega-spread" contentions and attempts to thwart discovery are flawed and misleading. The drugs at issue here are primarily inexpensive commodity products (such as sodium chloride and dextrose solutions) with "spreads" of less than $10 per dose. As recently stated by the Congressional Budget Office, "the dollar markup is a better indicator of the size or adequacy of Medicaid's reimbursements to pharmacies than is the percentage margin." CONGRESSIONAL BUDGE OFFICE, *Medicaid's Reimbursements to Pharmacies for Prescription Drugs* (Dec. 2004) at 3. Pharmacies and providers were paid with dollars, not percentages, and it is magnitude of the dollar markup that policy-makers should—and we believe did—assess when allowing the AWP-based system to compensate for inadequate dispensing and administration fees, encourage generic drug use, and ensure patient access to care.

[4] *See* Vito Tr. at 663-665 (Medicare increased the dispensing fee to inhalation drug suppliers from $5-6 to $57 in connection with the Medicare Modernization Act of 2003) (Ex. 2); HHD061-1146 (excerpts of draft MMA

knowingly used to cross-subsidize insufficient dispensing and professional fees—or if CMS or State Medicaid agencies decided not to increase dispensing or administration fees because of the spread paid on ingredient cost—such deliberate action could eviscerate the Government's claims here.

Indeed, in response to a January 2008 OIG report, CMS acknowledged that third-party payors, including Medicare and Medicaid, deliberately accept reasonable dollar margins on generic drugs to compensate for inadequate dispensing fees, encourage generic use, and ensure access to care. *See Review of the Relationship Between Medicare Part D Payments to Local, Community Pharmacies and The Pharmacies' Drug Acquisition Costs* (A-06-07-00107, Jan. 2008) at Appendix. G (last two pages) (Ex. 10). In this recent report, OIG studied the percentage difference between pharmacy acquisition costs and Medicare Part D payments. OIG found that the percentage difference between acquisition cost and Part D payment was nine times greater for generic drugs than brand-name drugs, but was careful to point out that "generic and brand-name drugs had similar per prescription dollar differences" ($9.12 and $9.18, respectively). *Id.* at 6.

The CMS response to this report is telling. Instead of claiming fraud due to the existence of an average $9 dollar spread, including what Government counsel would label "mega-spreads" for many generic drugs, CMS stated it was "*pleased* by the findings in this report that the private market contract model in Part D *provides margins* to community pharmacies with respect to their acquisition costs." *Id.* at Appendix G (emphasis added). CMS further commented that OIG's findings were "expected as it is one method for pharmacies to *support the expense of dispensing*

(continued…)

2003 regulations show increase in administrative fees for "IV infusion therapy, 1 hour" from $40.54 to $89.92 and increase in administrative fee for "injection" from $3.98 to $24.64) (Ex. 9).

costs." *Id.* (emphasis added). Finally, in response to OIG's finding that the difference between cost and payment was nine times greater for generic drugs, CMS stated:

> Clinically appropriate generic prescribing is one of the key ways in which the Part D program is able to provide high quality coverage at a reasonable cost to both beneficiaries and the government. We fully encourage the use of generic drugs since their use provides good value to both the beneficiary and the taxpayer, *and we note that incentives are aligned* to encourage promotion of generics by community pharmacists.

Id. (emphasis added). One might ask how payment of a $9 margin over acquisition can be acceptable—even encouraged—in one instance, yet constitute a "false claim" in this case.

This is not the first time that state and federal governmental agencies have conveyed such sentiments:

- In a 1993 report, the GAO stated that while Medicaid payments exceeded drug costs, "[n]either HCFA nor the states have determined what would be an appropriate margin between reimbursements and costs." GAO, *Outpatient Drug Costs and Reimbursements for Selected Pharmacies in Illinois and Maryland* (Mar. 1993) at 6 (Ex. 11). GAO further stated that "HCFA officials also noted that . . . states . . . were not willing to increase dispensing fees regardless of survey results" and "HCFA and state Medicaid officials agreed that pharmacies must often use excess Medicaid reimbursements to cover their dispensing costs." *Id.*

- Responses by the state Medicaid programs to OIG's work in the mid-1990s—which found an average discount from AWP for generic drugs of 42.5% (58% for nursing home and home infusion pharmacies)—paint a similar picture. For example, Montana was worried that OIG's report would prompt immediate calls to reduce reimbursement to pharmacies, even though Montana "believe[d] that the dispensing [fee was] below the cost to dispense because of the cap on dispensing fees." *Review of Pharmacy Acquisition Costs of the Montana DPHHS* (July 11, 1996) (Ex. 12). In a similar response, Missouri stated that "ingredient cost is only one component to be considered in determining a pharmacy reimbursement level," and noted that dispensing fees paid by the state had not been raised to recommended levels. *Review of Pharmacy Acquisition Costs of the Missouri DSSS* (Jan. 1997) (Ex. 13).

- In a 2005 testimony, the CBO noted that pharmacies receive "markups" on generic drugs equal to or larger than markups on brand-name drugs. The CBO noted that "[m]aintaining such incentives might be an important consideration in assessing Medicaid's payment system for prescription drugs." Statement of Douglas Holtz-Eakin, *Payments for Prescription Drugs Under Medicaid*, Before the Special Committee on Aging, United States Senate (July 20, 2005) (Ex. 14).

- In 2004, the research firm Abt reported the results of a CMS-sponsored conference of pharmaceutical industry experts that included CMS and OIG personnel (Deirdre Duzor and Robert Vito). *See Medicaid and Medicare Drug Pricing: Strategy to Determine Market Prices* (Aug. 30, 2004) (Ex. 15) (excerpts). In that report, Abt stated: "Most experts agree that AWP, or even the typical discounts to AWP, exceed actual acquisition costs for both pharmacies and physicians. This is particularly true for generic drugs. At the same time, these experts agree that Medicaid dispensing fees are low relative to actual dispensing costs. . . . Payments based on the cost structure experience by pharmacies may warrant payment of a reasonable and managed spread (and amount paid above the actual acquisition cost), in addition to a fixed dispensing fee and an appropriate service fee for medication therapy management." *Id.* at 7.

Such evidence indicates that state and federal officials were not misled into paying "excessive reimbursement" (Compl. ¶ 3) for the drugs at issue here. Rather than creating a system that would have paid accurately for both acquisition costs of drugs as well as costs incurred incident to their administration, policy-makers instead chose to perpetuate an inefficient, haphazard system that roughly approximated the total costs incurred by providers. This story, of course, negates the Government's theory that Abbott caused providers to submit false claims for payment.[5] It shows instead that the alleged overpayments described in the Complaint were actually caused by the deliberate inaction of a Government fully aware of the consequences for its complacency. Abbott is entitled to ask deposition witnesses whether their memories confirm this story.

[5] *See United States ex rel. A+ Homecare, Inc. v. Medshares Mgmt. Group, Inc.*, 400 F.3d 428, 445 (6th Cir.) (if the "plaintiff cannot show that the government agency would have acted differently had it known of the omission, 'there is no false claim because [the agency's action] would have occurred regardless of [the defendant's] actions'") (*quoting Rabushka ex rel. United States v. Crane Co.*, 122 F.3d 559, 563 (8th Cir. 1997)) (alterations in original), *cert. denied*, 126 S. Ct. 797 (2005)); *Mikes v. Straus*, 274 F.3d 687, 697 (2d Cir. 2001) ("Since the [False Claims] Act is restitutionary and aimed at retrieving ill-begotten funds, it would be anomalous to find liability when the alleged noncompliance would not have influenced the government's decision to pay."); *United States ex rel. Gudur v. Deloitte Consulting LLP*, No. H-00-1169, 2007 WL 836935, *11 (S.D. Tex. March 15, 2007) ("no violation exists where relevant government officials are informed of the alleged falsity, thus precluding a determination that the government has been deceived"); *United States ex rel. Lamers v. City of Green Bay*, 998 F. Supp. 971, 988 (E.D. Wis. 1998) ("no violation [of the FCA] exists where the government has not been deceived"), *aff'd*, 168 F.3d 1013 (7th Cir. 1999).

II. THE GOVERNMENT HAS FAILED TO ARTICULATE ANY LEGITIMATE HARM THAT WOULD RESULT FROM ALLOWING RESPONSES TO ABBOTT'S QUESTIONING, AND THE BALANCE TIPS HEAVILY IN FAVOR OF COMPELLING THE OBSTRUCTED TESTIMONY.

For the reasons set forth in Abbott's prior briefing on the deliberative process privilege and the cases cited therein (*see* Dkt. Nos. 3513, 3594 & 3960), the Government's role as plaintiff here renders it unable to withhold evidence under the deliberative process privilege. It should not be permitted to obstruct deposition testimony any more than any other litigant could under the Federal Rules.

Moreover, even under a balancing test, the balance tips decidedly in favor of disclosure. When each factor is given full consideration, it becomes clear that the vague deliberative process claims made by the Government's lawyers are insufficient in light of the clear relevance and importance of the material that the Governments seeks to withhold.

The first factor of the balancing test, the relevance of the material sought, is addressed above and in Abbott's prior briefing. In short, the Government is withholding evidence that sheds light on why Government officials continued to rely on published drug prices despite extensive knowledge that they did not represent a reliable indication of acquisition costs.

The second consideration, the availability of other evidence, also supports disclosure of the testimony. The Government's delay in prosecuting this case has resulted in the loss of key evidence due to fading memories and the destruction of documents. The Government has produced relatively little from CMS's Central Office—where most, if not all, of the key decisions were made. (The rest of its production comes from secondary locations like CMS Regional Offices, OIG, and Medicare Part B carriers.) The reason Abbott has received such a paltry production from CMS is readily apparent: as detailed in Abbott's Motion for a Preservation Order (Dkt. No. 4711) presently pending before the Court, the Government did not

circulate a litigation document hold memorandum until 2007, and witness after witness has testified that their emails and files have been destroyed. *See* Dkt. No. 4711, at 2-7 (detailing the Government's destruction of documents, including emails, from key custodians, even after the this case was filed and subpoenas were issued to CMS). Abbott should be entitled to full discovery—including full, unfettered access to the memories of key federal government witnesses—of what evidence remains.

The third and fourth factors of the balancing test—the seriousness of the litigation and the role of the government in the litigation—are perhaps the most important factors for the Court to consider. *See United States v. Hooker Chems. & Plastics Corp.*, 123 F.R.D. 3, 12 (W.D.N.Y. 1988) ("Perhaps most importantly, the government asserting the privilege in this case is a party to the litigation."). The Government's role as plaintiff comes with certain costs, including the obligation to allow testimony relevant to Abbott's defenses. *See EEOC v. Airborne Express*, No. 98-1471, 1999 WL 124380, at *2 (E.D. Pa. Feb. 23, 1999) (finding it "fundamentally unfair" for the Government, as party plaintiff, to evade discovery of material that a private plaintiff would have to turn over and thus rejecting the Government's assertion of the deliberative process privilege) (internal quotation marks omitted).[6]

Finally, with respect to the fifth factor, the Government cannot articulate any concrete harm that would come to CMS if the testimony were allowed to go forward under a protective order in this case. The Government is required to articulate "precise and certain reasons for

[6] *See also United States v. Ernstoff*, 183 F.R.D. 148, 153 (D.N.J. 1998) (where the Department of Justice was plaintiff, the court rejected its assertion of the deliberative process privilege finding that "[c]ommon sense and basic fairness requires that [the withheld material] receive no greater protection than they would in the hands of a private litigant"); *Resolution Trust Corp. v. Diamond*, 773 F. Supp. 597, 605 n.7 (S.D.N.Y. 1991) (FTC's role as plaintiff "tends to open the door to discovery of FTC's decision-making processes"); *Dep't of Econ. Dev.*, 139 F.R.D. at 596 ("[T]he British Government's position as plaintiff in this case tips the balance of interests in favor of disclosure of the documents"; "by asserting a fraud against [defendant], the British Government necessarily places at issue questions of knowledge, justifiable reliance and causation") (internal quotation marks omitted).

preserving the confidentiality of the requested information." *See Mobil Oil Corp. v. Dep't of Energy*, 102 F.R.D. 1, 6 (N.D.N.Y. 1983) (internal quotation marks omitted). Thus far, the Government has done no more than offer general, conclusory remarks that merely parrot the general purpose of the deliberative process privilege. The Government will do no better this time around, and that is inadequate. *See Resolution Trust Corp. v. Diamond*, 773 F. Supp. 597, 604 (S.D.N.Y. 1991) (rejecting assertion of deliberative process privilege when Government's affidavits provide "merely a paraphrase of the rationale for the deliberative-process privilege described in the case law").

CONCLUSION

For the foregoing reasons, the Court should grant Abbott's Motion to Compel Deposition Testimony, overruling the assertions of deliberative process privilege lodged by Government counsel and ordering witnesses to answer the questions identified in Exhibit 1.

Dated: March 3, 2008

Respectfully submitted,

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CERTIFICATE OF SERVICE

I, David S. Torborg, an attorney, hereby certify that I caused a true and correct copy of the foregoing ABBOTT'S MEMORANDUM IN SUPPORT OF ITS MOTION TO COMPEL TESTIMONY FROM GOVERNMENT WITNESSES to be served on all counsel of record electronically by causing same to be posted via LexisNexis, this 3rd day of March, 2008.

/s/ David S. Torborg
David S. Torborg